DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

CeloNova Biosciences, Inc.
Nicole Barber
Manager, Regulatory Affairs
18615 Tuscany Stone, Suite 100
San Antonio, TX 78258

Re: K141209
Trade/Device Name: Embozene Color-Advanced Microspheres; Embozene Opaque (Non-Colored) Microspheres; Oncozene Microspheres
Regulation Number: 21 CFR§ 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: KRD, NAJ
Dated: May 7, 2014
Received: May 9, 2014

Dear Nicole Barber,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) _____

Device Name **Embozene® Microspheres**

Indications for Use **Embozene® Microspheres are indicated for the embolization of arteriovenous malformations and hypervascular tumors including uterine fibroids and hepatoma.**

Prescription Use___X_____ AND/ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use Statement

510(k) Number (if known) _____

Device Name **ONCOZENE™ Microspheres**

Indications for Use **ONCOZENE™ Microspheres are indicated for the embolization of arteriovenous malformations and hypervascular tumors including hepatoma.**

Prescription Use___X_____ AND/ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary of Safety and Effectiveness

Summary Date: May 7, 2014

Submitter: CeloNova BioSciences, Inc.
18615 Tuscany Stone, Ste. 100
San Antonio
Texas 78258, USA

Contact: Nicole C. Barber
Manager, Regulatory Affairs

1. Common name, Trade name & Classification of Subject Device

Trade Name:	Embozene® Microspheres and ONCOZENE™ Microspheres
Common Name(s):	Vascular Embolization device, embolization, arterial
Product Code:	KRD, 21 CFR 870.3300
Classification:	Class II (special controls)

2. 510(k) Numbers and Product Codes of Predicate Devices

Trade Name:	Embozene® Microspheres
Manufacturer:	CeloNova BioSciences, Inc.
510(k) Number:	K073417/ K132675/K133447
Product Code:	KRD, NAJ, 21 CFR 870.3300

Trade Name:	ONCOZENE™ Microspheres
Manufacturer:	CeloNova BioSciences, Inc.
510(k) Number:	K130307
Product Code:	KRD, 21 CFR 870.3300

3. Indications for Use and Intended Purpose

The modification that is the subject of this 510(k) submission affects two legally marketed CeloNova BioSciences' medical devices; Embozene® Microspheres and ONCOZENE™ Microspheres. The modified indications for use statements for each of these medical devices are as follows:

> Embozene® Microspheres are intended for embolization of arteriovenous malformations, and hypervascular tumors, including uterine fibroids and hepatoma.[1]
>
> ONCOZENE™ Microspheres are intended for embolization of arteriovenous malformations, and hypervascular tumors, including hepatoma.

4. Device Description

Embozene® Microspheres and ONCOZENE™ Microspheres are tightly calibrated, compressible microspheres intended to occlude vasculature for the purpose of blocking blood flow to a target tissue such as a hypervascular tumor (HVT) or arteriovenous malformation (AVM). The microspheres are manufactured from sodium polymethacrylate and coated with proprietary Polyzene®-F. The microspheres are compressible to enable smooth delivery through the indicated delivery catheter. Embozene® Microspheres are available opaque or color coded by size to allow easy identification of the different sizes; ONCOZENE™ Microspheres are available in opaque only.

Embozene® / ONCOZENE™ Microspheres are supplied sterile and packaged in 20ml polycycloolefin syringes with a standard 7ml fill volume across the range. Embozene® Microspheres syringes or vials are available in 1 ml or 2 ml microsphere volume; ONCOZENE™ Microspheres are available in 2 ml or 3 ml microsphere volume. Product configurations are shown in the following tables.

Product REF Codes for Embozene® Color-Advanced Microspheres in Syringe and Vial

Product REF Codes Embozene® Color-Advanced Microspheres		***Volume of Embozene® Color-Advanced Microspheres per Syringe***		***Volume of Embozene® Color-Advanced Microspheres per Vial***	
Nominal Size	Specifications	1ml	2ml	1ml	2ml
40 µm	40 µm ±10 µm	10410-S1	10420-S1	10401-V1	10402-V1
75 µm	75 µm ±15 µm	10710-S1	10720-S1	10701-V1	10702-V1
100 µm	100 µm ±25 µm	11010-S1	11020-S1	11001-V1	11002-V1
250 µm	250 µm ± 50 µm	12010-S1	12020-S1	12001-V1	12002-V1
400 µm	400 µm ± 50 µm	14010-S1	14020-S1	14001-V1	14002-V1
500 µm	530 µm ± 50 µm	15010-S1	15020-S1	15001-V1	15002-V1

[1] The indications for use statement is different for ONCOZENE™ Microspheres since the sizes available are not applicable to uterine fibroid embolization.

700 µm	700 µm ± 50 µm	17010-S1	17020-S1	17001-V1	17002-V1
900 µm	900 µm ± 75 µm	19010-S1	19020-S1	19001-V1	19002-V1
1100 µm	1100 µm ± 75 µm	111010-S1	111020-S1	111001-V1	111002-V1
1300 µm	1300 µm ± 75 µm	113010-S1	113020-S1	113001-V1	113002-V1

Product REF Codes for Embozene® Opaque (Non-Colored) Microspheres in Syringe and Vial

Product REF Codes Embozene® Opaque Microspheres		***Volume of Embozene® Opaque Microspheres per Syringe***		***Volume of Embozene® Opaque Microspheres per Vial***	
Nominal Size	Specifications	1ml	2ml	1ml	2ml
40 µm	40 µm ±10 µm	10410-S0	10420-S0	10401-V0	10402-V0
75 µm	75 µm ±15 µm	10710-S0	10720-S0	10701-V0	10702-V0
100 µm	100 µm ±25 µm	11010-S0	11020-S0	11001-V0	11002-V0
250 µm	250 µm ± 50 µm	12010-S0	12020-S0	12001-V0	12002-V0
400 µm	400 µm ± 50 µm	14010-S0	14020-S0	14001-V0	14002-V0
500 µm	530 µm ± 50 µm	15010-S0	15020-S0	15001-V0	15002-V0
700 µm	700 µm ± 50 µm	17010-S0	17020-S0	17001-V0	17002-V0
900 µm	900 µm ± 75 µm	19010-S0	19020-S0	19001-V0	19002-V0
1100 µm	1100 µm ± 75 µm	111010-S0	111020-S0	111001-V0	111002-V0
1300 µm	1300 µm ± 75 µm	113010-S0	113020-S0	113001-V0	113002-V0

ONCOZENE™ Microspheres Specifications

Product REF Codes ONCOZENE™ Microspheres		***Volume of ONCOZENE™ Microspheres per Syringe***	
Nominal Size	**Specifications**	**2 ml**	**3 ml**
40 µm	40 µm ± 10 µm	10420-US1	10430-US1
75 µm	75 µm ± 15 µm	10720-US1	10730-US1
100 µm	100 µm ± 25 µm	11020-US1	11030-US1

5. Similarities and Differences Compared to Predicate Devices

The Embozene® Microspheres that are the subject of this 510(k) are the same as the legally marketed Embozene® Microspheres, previously cleared by FDA, in regard to intended use and technological characteristics. The only difference between the subject of this 510(k) and our legally marketed predicate devices relates to the indications for use statement. The indications for use statement related to this 510(k) includes greater specificity than our predicates by explicitly identifying "hepatoma" as being among the tumors treated with vascular embolization devices, as established by 21 CFR § 870.3300.

6. Summary of Technological Characteristics

Comparison between the Subject Devices (Embozene® and ONCOZENE™) and the Predicate Devices (Embozene® and ONCOZENE™)

	Subject Embozene® and ONCOZENE™ Microspheres	**Predicate Embozene® and ONCOZENE™ Microspheres**
Administrative Elements		
Manufacturer	CeloNova BioSciences, Inc.	CeloNova BioSciences, Inc.Same
Premarket Notification	To be assigned by FDA	K073417 and K132675
Classification	Class II (special controls)	Class II (special controls)
Classification Regulation	21 CFR 870.3300	21 CFR 870.3300
Product Code	KRD - Device, Vascular, For Promoting Embolization	KRD - Device, Vascular, For Promoting Embolization
	NAJ- Agents, Embolic, For Treatment Of Uterine Fibroids (Embozene only)	NAJ- Agents, Embolic, For Treatment Of Uterine Fibroids (Embozene only)
Intended Use		
Indications for Use Statement	Embozene® Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids **and hepatoma**.* ONCOZENE™ Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors **including hepatoma**.*	Embozene® Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids. ONCOZENE™ Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors.
Method of Delivery	Microcatheter under fluoroscopic visualization with contrast	Same
OTC or Rx	Rx	Same
Technological Characteristics		
Mechanism of Action	Mechanical Occlusion	Same
Material Class	Crosslinked polyacrylate hydrogel	Same
Material Design	Spherical	Same
Material Composition	Crosslinked polyacrylate hydrogel with Polyzene-F	Same

Sizes [µm]	40 ± 10 75 ± 15 100 ± 25 250 ± 50 400 ± 50 530 ± 50 700 ± 50 900 ± 75 1100 ± 75 1300 ± 75 Sizes 250 - 1300 are available for Embozene Only	Same
Biocompatibility of patient-contacting materials	Yes	Same
Microsphere Volume [ml]	Embozene: 1 or 2 ONCOZENE: 2 or 3	Same
Sterility Assurance Level	Supplied sterile to SAL 10^{-6}	Same
Pyrogen-free	Yes	Same
Packaging	Syringe or vial (vial for Embozene only)	Same
Shelf-life	3 years	Same

7. Summary of Non-Clinical Performance Testing

There are no performance standards applicable to the device. The device is subject Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices issued on December, 29 2004. Non-clinical performance testing conducted on the predicate device includes:

- Chemical analysis
- Size range
- Catheter compatibility
- Density
- Packaging performance
- Shelf Life
- Sterility
- Biocompatibility

No new testing was conducted since the predicate device and the subject device have identical technological characteristics, manufacturing, processing, and sterilization.

8. Summary of Clinical Experience

The clinical information submitted included a review of embolization using various embolic agents to physically occlude vessels to restrict blood flow over the last ten years, published and unpublished data on the use of use of Embozene® for the treatment of hypervascular tumor including hepatoma (outside the United States) and postmarket experience with the cleared device.

Review of published and unpublished data regarding adverse events associated with Embozene® Microspheres and ONCOZENE™ Microspheres did not identify any unique safety concerns regarding use of Embozene® Microspheres and ONCOZENE™ Microspheres for hepatoma embolization.

9. Conclusion

The Embozene® Microspheres and ONCOZENE™ Microspheres that are the subject of this 510(k) submission are substantially equivalent to the two predicate devices (Embozene® Microspheres K073417/K132675/K133447 and ONCOZENE™ Microspheres K130307) when indicated for the more general intended use of embolization of hypervascular tumors. The data on hepatoma embolization are sufficient to support the safety and effectiveness of Embozene® Microspheres and ONCOZENE™ Microspheres for embolization of hepatoma.